

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS LIABILITY  
LITIGATION

MDL No. 2419

THIS DOCUMENT RELATES TO:

Dkt. No. 1:13-md-2419 (RWZ)

All Suits Naming Specialty Surgery Center;  
Kenneth R. Lister, M.D.; and Kenneth Lister,  
M.D., P.C.

**PLAINTIFFS’ STEERING COMMITTEE’S OPPOSITION  
TO SSC DEFENDANTS’ MOTION FOR SUMMARY JUDGMENT  
ON PLAINTIFFS’ CLAIMS FOR STRICT PRODUCT LIABILITY**

The SSC Defendants have moved for summary judgment on the Plaintiffs’ claims under the Tennessee Products Liability Act, Tenn. Code. Ann. § 29-26-101 *et seq.* (the “PLA”), contending that the Court should simply apply its February 29, 2016, Order and Opinion in the Saint Thomas matters to the SSC Defendants here. The motion should be denied for multiple reasons.

**INTRODUCTION**

The Plaintiffs respectfully maintain that Plaintiffs’ PLA claims should be allowed to proceed. Under Tennessee law and principles of statutory construction, the PLA and the Tennessee Health Care Liability Act (“HCLA”) can (and therefore must) be read in harmony under the facts presented in these cases. Furthermore, both the legislative history and policy considerations support permitting both claims to proceed.

The Court’s February 29, 2016 Order and Opinion in the Saint Thomas matters is not dispositive of the SSC Defendants’ Rule 56 motion. In that earlier opinion, the Court incorrectly stated that the plaintiffs in those cases had conceded that the HCLA was the more specific statute

as it applied to the facts at issue, and held that in light of that supposed concession the PLA claims should be dismissed. The PSC never made that concession there, and it explicitly does not make that concession here. Instead, as explained herein, the PSC contends the PLA is the more specific statute as it relates to the product sales by the SSC Defendants. Thus, the Court's earlier opinion in the Saint Thomas matters, whatever its merits (and its misapprehension of the PSC's actual legal positions in those matters), does not control here.

Furthermore, unlike the Saint Thomas Defendants, the SSC Defendants have presented only a handful of purportedly undisputed facts to support their motion, none of which relate to the actual sales of products by the defendants that created liability under the PLA. Indeed, as the Plaintiffs' accompanying Rule 56.1 Counter-Statement of Facts demonstrates, the facts show that the defendants did sell MPA to patients in exchange for money, as SSC's Administrator Kim Bowlin testified explicitly.<sup>1</sup>

Thus, in light of the facts presented in these particular cases, and the PSC's explicit positions articulated herein, the Court must review the plaintiffs' arguments set forth herein independently of its earlier decision and on their own merits. The PSC maintains that, after

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<sup>1</sup> The Court should also be aware that common fact discovery of the SSC Defendants is not complete. In addition to other common fact to which the PSC may be entitled, the Court has already ruled that the PSC is entitled to re-depose Jean Atkinson and defendant Dr. Kenneth Lister. The PSC also anticipates receiving additional records based on forthcoming motion practice relating to the SSC Defendants' unsupported claims of privilege, the PSC may notice additional depositions, and (once the Court rules on pending cross-motions relating to the data on the computers) the PSC will be receiving additional records from seven computers in the possession of Cumberland Medical Center that SSC had transferred as part of an asset sale in June 2013. It may be that this discovery will result in additional facts that support the PSC's contention that the SSC Defendants' sold products to the plaintiffs within the meaning of the PLA. The PSC reserves the right to supplement this response or seek reconsideration of this Court's disposition of this motion based on any newly discovered evidence.

conducting that independent analysis, the Court will determine that the Plaintiffs' products claims can proceed alongside the HCLA claims.

Second, even if the Court were inclined to graft its February 2016 Order and Opinion onto these cases, circumstances have changed. The question of whether a patient can bring a strict products liability action against an ambulatory surgery center for an injury sustained during an epidural steroid injection procedure – in other words, the very question at issue here – has been certified to the Tennessee Supreme Court and is currently awaiting determination by that court. In light of that certification, the issue of law that the SSC Defendants' motion presents is not settled. Under similar circumstances, this Court and other federal courts have found that the more prudent course is for the district court to abstain from deciding an unsettled matter of state law while the state's highest court considers it. In the meantime, allowing the parties to proceed on both legal theories would add no substantial additional discovery and would consume no significant additional trial time. Conversely, granting summary judgment pre-trial, and not allowing the jury to consider the separate PLA claim, would potentially necessitate re-trials if the Tennessee Supreme Court rules in favor of the Plaintiffs on this unsettled issue of Tennessee law.

## **FACTUAL BACKGROUND**

### **I. The Fungal Meningitis Catastrophe**

This litigation arises from a fungal meningitis outbreak caused by contaminated steroids compounded in Massachusetts by the New England Compounding Pharmacy ("NECC"). Numerous clinics across the United States sold and distributed contaminated steroids to patients. To date, more than 750 people suffered fungal meningitis, fungal infections and/or abscesses as a

result of the contaminated steroids, and at least 64 people died.<sup>2</sup> The catastrophe impacted Tennessee with particular severity. The tainted steroids sickened 153 Tennesseans and killed 16 Tennesseans.<sup>3</sup>

As the PSC has previously shown, (1) compounding pharmacies, including NECC, were generally not regulated by the FDA, (2) the risks of pharmacy compounding were widely known before the fungal meningitis catastrophe; and (3) NECC had a history of regulatory non-compliance that served as a stark warning to would-be purchasers of NECC's pharmaceutical products.<sup>4</sup>

## **II. Facts Concerning the SSS Defendants**

The Defendants operated a high volume pain clinic that distributed hundreds of vials of Depo-Medrol to patients each year.<sup>5</sup> In 2012, Dr. Kenneth Lister was a part owner of SSC, Jean Atkinson was the Director of Nursing for SSC, and defendant Calisher & Associates ("Calisher") performed management services for SSC.<sup>6</sup> In 2012, Dr. Lister spearheaded SSC's high-volume injection practice, performing as many as 14 epidural steroid injections per day at SSC – the most that he could possibly schedule in a given workday – and about 40-60 injections per month.<sup>7</sup>

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<sup>2</sup> Rule 56.1 Plaintiffs' Counter-Statement of Facts ("PSOF No. X")

<sup>3</sup> PSOF No. 2.

<sup>4</sup> In previous motion practice related the Saint Thomas Entities, the PSC set demonstrated these facts with supporting evidence. *See* Dkt No. 2302 and Exhibits thereto. In the interest of efficiency and judicial economy, those same relevant facts are set forth in Appendix A hereto (as supported by Facts Nos. 1-17 of the accompanying Rule 56.1 Counter-Statement of Facts) and are incorporated by reference herein.

<sup>5</sup> PSOF No. 18.

<sup>6</sup> PSOF Nos. 19-21.

<sup>7</sup> PSOF Nos. 19 and 38. Dr. Lister was also the sole doctor at SSC who performed these injections. PSOF No. 34.

Until July 2012, SSC purchased Depo-Medrol from distributors that sold only FDA-approved pharmaceuticals.<sup>8</sup> Before July 2012, never purchased steroids from compounding pharmacies for use in epidural steroid injections.<sup>9</sup>

However, in July 2012, when prices for Depo-Medrol rose, SSC switched to purchasing compounded MPA in bulk from NECC.<sup>10</sup> SSC, Dr. Lister, and Calishers all participated in that decision.<sup>11</sup> Before switching to purchasing compounded MPA from NECC in July 2012, SSC, Dr. Lister, and Calisher essentially did no due diligence.<sup>12</sup> Also, although the SSC Defendants have claimed that there was a “shortage” of Depo-Medrol at the time, SSC had never failed to receive Depo-Medrol from a supplier in time for a scheduled injection procedure, and Calisher did not even contact any pharmaceutical wholesalers to determine whether a sufficient supply of Depo-Medrol was available.<sup>13</sup> Instead, they simply determined that NECC was offering a “good” price for compounded MPA and began purchasing from them.<sup>14</sup>

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<sup>8</sup> PSOF No. 25.

<sup>9</sup> PSOF No. 26.

<sup>10</sup> PSOF Nos. 22 and 27.

<sup>11</sup> PSOF No. 22.

<sup>12</sup> As set forth in PSF No. 23, they failed to (a) investigate whether NECC had any regulatory actions against them because of previous problems; (b) investigate whether NECC had a history of producing contaminated products; (c) investigate whether anyone state or federal agencies had made any complaints or taken any actions against NECC; (d) contact the Tennessee Department of Health about NECC; (e) Contact any state board of pharmacy about NECC; (f) consult with experts or attorneys concerning regulatory compliance issues, the safety of compounding pharmacies, and the legality of purchasing from them in bulk; (g) research the differences between compounded pharmacies and FDA-licensed distributors; (h) conduct a Google search of NECC; (i) visit NECC’s facilities; (j) review of FDA publications and warnings, media articles, or medical literature regarding the dangers of compounded drugs, (k) research concerning the safety and risks of compounded medications; and (l) verify information contained in NECC’s promotional literature.

<sup>13</sup> PSOF No. 29.

<sup>14</sup> PSOF No. 30.

Between July 2012 and September 2012, SSC purchased hundreds of vials of preservative-free MPA from NECC, and did so without filling out a valid patient-specific prescription for each patient who received an injection of NECC-compounded MPA.<sup>15</sup> In spite of all of these issues, Dr. Lister did not inform the patients that they were receiving MPA purchased from a compounding pharmacy or that the MPA did not contain preservatives.<sup>16</sup>

The Defendants operated SSC as a for-profit corporation,<sup>17</sup> and the epidural steroid injection practice that Dr. Lister performed at SSC constituted approximately a third of SSC's procedural volume between January 2012 and September 2012.<sup>18</sup> When the Defendants performed an epidural steroid injection, they expected to be paid for each injection, and Dr. Lister and SSC each charged and received separate payments associated with the injection.<sup>19</sup> Specifically, as the defendants' Administrator Kim Bowlin acknowledged at her deposition, the defendants **provided epidural steroid injections to patients in exchange for money.**<sup>20</sup> Indeed, SSC's payment for the injection included charges for the steroid itself.<sup>21</sup>

The amount of money that SSC was able to retain in profit from each injection varied based on the price of the steroid used. In other words, if SSC paid less for the steroid product used in a particular injection, it would have retained more of the reimbursement amount associated with that injection.<sup>22</sup> SSC therefore had a financial incentive to purchase steroids at

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<sup>15</sup> PSOF No. 31-32.

<sup>16</sup> PSOF Nos. 44 and 45.

<sup>17</sup> PSOF No. 33.

<sup>18</sup> PSOF No. 39.

<sup>19</sup> PSOF Nos. 34, 37, 40.

<sup>20</sup> PSOF No. 36.

<sup>21</sup> PSOF No. 41.

<sup>22</sup> PSOF Nos. 42 and 43.

the lowest price, so as to maximize profit when it sold the steroids to patients for use in epidural steroid injections.

### **ANALYSIS**

The Court will recall that it addressed a similar issue in its February 2016 Order where the parties in the St. Thomas cases moved for summary judgment on the plaintiff's product liability claims under the PLA.<sup>23</sup> Central to the Court's February Order when it addressed a similar motion for summary judgment involving the St. Thomas Defendants was the Court's finding that the plaintiffs conceded that the HCLA was a "more specific" statute than the PLA.<sup>24</sup> The PSC in the St. Thomas cases respectfully disagrees that it made such concession then and it certainly does not make that concession now. Under basic rules of statutory construction, the PSC maintains that plaintiffs in the SSC cases can maintain a claim under the PLA against the SSC Defendants, notwithstanding the language in the HCLA.

In any event, even if this Court were inclined to follow its February Order, the PSC maintains that circumstances have now changed and believes that since the issue is now before the Tennessee Supreme Court that the Court should deny summary judgment, as consistent with the precedent within this district.

#### **I. Tennessee's Principles of Statutory Construction**

In construing a statute, the Court must ascertain and give effect to the legislative intent without unduly restricting or expanding a statute's coverage beyond its intended scope.<sup>25</sup> "It is the duty of a court 'to construe a statute so that no part will be inoperative, superfluous, void or

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<sup>23</sup> Dkt. No. 2700.

<sup>24</sup> Dkt. No. 2700 at P. 5.

<sup>25</sup> *Lee Med., Inc. v. Beecher*, 312 S.W.3d 515, 541 (Tenn. 2010) (citing *Owens v. State*, 908 S.W.2d 923, 926 (Tenn. 1995)).

insignificant, and the one section will not destroy another; and further to give effect to every word, phrase and sentence of the act in order to carry out the legislative intent.”<sup>26</sup> Furthermore, in discerning legislative intent, courts employ the principle of *expressio unius est exclusio alterius*, which provides that “where the legislature includes particular language in one section of a statute but omits it in another section of the same act, it is generally presumed that the legislature acted purposefully in the subject included or excluded.”<sup>27</sup>

When a court is asked to construe the interaction between two statutes, several principles apply. First, a construction that places “one statute in conflict with another must be avoided; therefore, [a court] must resolve any possible conflict between statutes in favor of each other, so as to provide a harmonious operation of the laws.”<sup>28</sup> Indeed, the Tennessee Legislature actually codified that central premise of statutory construction by providing as follows in the Tennessee Code: “[i]f provisions of different titles or chapters of the code appear to contravene each other, the provisions of each title or chapter shall prevail as to all matters and questions growing out of the subject matter of that title or chapter.”<sup>29</sup> Second, “[w]here a conflict is presented between two statutes, a more specific statutory provision takes precedence over a more general provision.”<sup>30</sup> Third, “the repeal of a statute by implication is not favored and there must be an

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<sup>26</sup> *Faust v. Metro. Gov’t of Nashville & Davidson Cnty.*, 206 S.W.3d 475, 489 (Tenn. Ct. App. 2006) (quoting *Tidwell v. Collins*, 522 S.W.2d 674, 676-77 (Tenn. 1975)).

<sup>27</sup> *In re Kaliyah S.*, 455 S.W.3d 533, 554 (Tenn. 2015) (quotation omitted).

<sup>28</sup> *Graham v. Caples*, 325 S.W.3d 578, 582 (Tenn. 2010) (internal brackets and quotation omitted) (emphasis added); *see also State ex rel. Metro. Gov’t of Nashville v. Spicewood Creek Watershed Dist.*, 848 S.W.2d 60, 62 (Tenn. 1993) (“[C]ourts should avoid a construction which places one statute in conflict with another,” and “potential conflicts between statutes should be resolved in favor of each statute, if possible, to provide a harmonious operation of the laws”) (citing *Parkridge Hosp., Inc. v. Woods*, 561 S.W.2d 754, 755 (Tenn. 1978)).

<sup>29</sup> Tenn. Code Ann. § 1-3-103 (emphasis added).

<sup>30</sup> *Graham*, 325 S.W.3d at 582.

irreconcilable conflict or repugnancy between the statutes that is plain and unavoidable to work a suspension of the earlier statute.”<sup>31</sup>

Here, all three factors, the legislative history, and policy considerations indicate that the PLA claims should proceed alongside the HCLA claims.

## **II. Plaintiffs May Assert Claims Under Both The PLA and the HCLA.**

### **A. The PLA: the More Specific Statute as to Products Liability Allegations**

The Tennessee Products Liability Act of 1978, codified at Tenn. Code Ann. § 29-28-101 *et seq.*, expressly authorizes claims for strict tort liability against sellers of defective or unreasonably dangerous products in certain limited circumstances, including when a product manufacturer is judicially declared insolvent.<sup>32</sup> The primary purpose of providing for seller liability “is to insure that where the manufacturer is insolvent, an injured party may look to a solvent seller for his losses.”<sup>33</sup>

The statute sets forth the grounds for a strict liability cause of action against a “seller” or “distributor” of a product, and defines those terms broadly. A “[s]eller includes a retailer, wholesaler, **or distributor**, and means **any individual or entity engaged in the business of selling a product**, whether such a sale is **for resale**, or **for use or consumption**.”<sup>34</sup> This provision does not contain any qualifying language before the phrase “entity engaged in the

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<sup>31</sup> *Oliver v. King*, 612 S.W.2d 152, 154 (Tenn. 1981); *see also Spence v. Miles Lab.*, 810 F. Supp. 952, 963-64 (E.D. Tenn. 1992) (finding no irreconcilable conflict between TPLA and a section of the Tennessee Code specific to the handling of AIDS-contaminated blood products, and construing statutes to be “harmonious”).

<sup>32</sup> Tenn. Code Ann. § 29-28-106(5).

<sup>33</sup> *Seals v. Sears, Roebuck and Co., Inc.*, 688 F. Supp. 1252, 1256 (E. D. Tenn. 1988).

<sup>34</sup> Tenn. Code Ann. § 29-28-102(7) (emphases added).

business of selling of a product.” A “product” means “any tangible object or goods produced.”<sup>35</sup>

There is no dispute that the MPA at issue was a “product” under the PLA.

The PLA also defines a “product liability action” broadly:

“Product liability action” for purposes of this chapter **includes all actions** brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product. “Product liability action” includes, **but is not limited to, all actions** based upon the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or **under any other substantive theory in tort or contract whatsoever.**<sup>36</sup>

As the plain language indicates, the PLA is written to encompass “all actions” involving personal injuries caused by “products” under “any substantive theory in tort or contract whatsoever.”

That provision is specific to the act selling (or reselling) products to a person or entity.

The PLA also contains certain limitations. Among other restrictions, it generally forbids a product liability action against “any seller, other than the manufacturer,” unless (in relevant part) the manufacturer has been judicially declared insolvent.<sup>37</sup> In other words, the general rule is that only the manufacturer of a product can be held liable for harm caused by the product. However, when the manufacturer is insolvent (*i.e.*, is judgment-proof and cannot make the victim whole) or cannot be served with process, sellers are required to stand behind the product

<sup>35</sup> Tenn. Code Ann. § 29-28-102(5).

<sup>36</sup> Tenn. Code Ann. § 29-28-102(6) (emphases added); *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 391 (6th Cir. 2013).

<sup>37</sup> Tenn. Code Ann. § 29-28-106(a)(3). The TPLA also exempts from its coverage breach of warranty actions otherwise covered by Tenn. Code Ann. § 47-2-101 *et seq.* (Tennessee’s adoption of the Uniform Commercial Code Sales) and actions in which the manufacturer cannot be served with process and is otherwise not subject to service under the long-arm statute.

which they chose to sell, and they are required make innocent tort victims legally whole. The language of § 29-28-106(a)(3) does not contain any exceptions for particular industries.

**B. Unique Provisions Contained in the PLA Reveal that Healthcare Providers Can be Product Sellers.**

The PLA contains a statutory carve-out indicating that there is one circumstance and only one circumstance in which healthcare providers are not considered sellers of dangerous or defective products: when the product is a silicone breast implant.<sup>38</sup> In all other circumstances, Tennessee healthcare providers are subject to the same degree of seller liability as all other Tennessee businesses who sell harmful products.

Section 103(c) of the PLA sets forth an extended statute of repose for actions against manufacturers or sellers of silicone breast implants.<sup>39</sup> The statute then carves out healthcare providers from the definition of the term “seller” for purposes of breast implant litigation only. Specifically, Section 103(c) provides:

(c)(1) Any action against a manufacturer or seller for injury to a person caused by a silicone gel breast implant must be brought within a period not to exceed twenty-five (25) years from the date such product was implanted; provided, that such action must be brought within four (4) years from the date the plaintiff knew or should have known of the injury.

(2) *For purposes of this subsection (c) only*, “seller” does not include a hospital or other medical facility where the procedure took place, nor does “seller” include the physician or other medical personnel involved in the procedure.

(3) This subsection (c) only applies to causes of action not pending or decided on or before May 26, 1993. For the purposes of this subsection (c), a “pending case” is defined as a case actually filed by a silicone gel-filled breast implant recipient.<sup>40</sup>

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<sup>38</sup> Tenn. Code Ann. § 29-28-103(c).

<sup>39</sup> Tenn. Code Ann. § 29-28-103(c)(1).

<sup>40</sup> Tenn. Code Ann. § 29-28-103(c)(emphasis added).

That specific and limited exclusion demonstrates that the Tennessee legislature knew and intended that healthcare providers (*e.g.*, medical facilities and medical personnel) may be held liable as “sellers” in cases involving products *other than* silicone breast implants. Otherwise, the statutory carve-out would be completely superfluous and of no effect. Under the rules of statutory construction, therefore, that one specific exclusion means that seller liability for healthcare providers is not excluded in cases involving any products other than silicone breast implants.<sup>41</sup>

Here, the epidural steroid injections at issue are akin to those involved in a breast implantation: when a medical provider charges a fixed fee for a breast implantation (including the service and the cost of the implant), the cost of the implant constitutes only a small percentage of the total cost. Under the doctrine of *expressio unius*, the fact that the legislature identified that particular procedure for an exemption to the term “seller” indicates that it otherwise intended for the PLA to cover injuries caused by defects in other products used in medical procedures, even when the product price reflects only a fraction of the overall charge for the procedure.

The facts here demonstrate that the SSC Defendants sold MPA to patients from July 2012 through September 2012. One of SSC’s own witnesses has explicitly acknowledged that SSC sold MPA to patients in exchange for money. Indeed, SSC sold the MPA for profit as a

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<sup>41</sup> As discussed above, a well-established rule of statutory construction is “the maxim ‘*expressio unius est exclusio alterius*,’ which states the principle that the expression of one thing implies the exclusion of all things not expressly mentioned.” *Limbaugh v. Coffee Med. Ctr.*, 59 S.W.3d 73, 84 (Tenn. 2001). According to the Tennessee Supreme Court, “the mention of one subject in a statute means the exclusion of other subjects that are not mentioned. Omissions are significant when statutes are express in certain categories but not others.” *Carver v. Citizen Utilities Co.*, 954 S.W.2d 34, 35 (Tenn. 1997) (citations omitted).

substantial portion of its business volume, SSC did so with the expectation of payment for those sales, and the SSC Defendants all profited from those sales.

### C. The HCLA's Focus On Healthcare Services

Briefly, the HCLA defines a “health care liability action” as “any civil action . . . alleging that a health care provider or providers have caused an injury **related to the provision of**, or failure to provide, **health care services to a person**, regardless of the theory of liability on which the action is based.”<sup>42</sup> The statute states that “health care services to persons” includes “care by health care providers which includes care by physicians, nurses, licensed practical nurses, pharmacists, . . . and other agents, employees, and representatives of the provider . . .”<sup>43</sup> The Act states that “any such civil action or claim is subject to this part regardless of any other claims, causes of action, or theories of liability alleged in the complaint[.]” Among other things, the HCLA provides that a health care liability action can be proven by showing that (1) the defendant owed a duty of reasonable care to the claimant and breached that duty; and (2) the breach of that duty is the legal cause of the claimant’s injury.<sup>44</sup>

The HCLA does not state, and no court has ever stated, that strict liability claims relating to medical **products** (as distinct from medical **services**) are precluded.

### D. Interaction Between the HCLA and the PLA Reveals That Plaintiffs May Assert Claims Under the PLA Without Undermining the HCLA

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<sup>42</sup> Tenn. Code Ann. § 29-26-101(a)(1) (emphases added).

<sup>43</sup> Tenn. Code Ann. § 29-26-101(b).

<sup>44</sup> Tenn. Code Ann. § 29-26-102(b)(2).

Under Tennessee rules of statutory construction and the asserted conflicts between two Tennessee statutes, the question the Court must resolve is: Can the language of the HCLA and the PLA be reconciled?

The answer is to that question is yes. Both the HCLA and PLA are all-encompassing within their spheres: the HCLA exclusively governs claims against a medical provider as they relate to medical services themselves, while the PLA exclusively governs claims against product sellers for harm caused by defective products if and when the product maker is insolvent. In other words, the HCLA governs claims arising from services provided by healthcare providers, while the PLA governs claims that have nothing to do with the healthcare providers' conduct or services, *i.e.*, claims for harm caused by products.

Plaintiffs' claims here under the PLA involve strictly allegations that MPA injected into plaintiffs was unreasonably dangerous/defective and caused plaintiffs' personal injuries. Those claims do not involve whatsoever the medical judgment of the medical providers.<sup>45</sup> Here, in August and September 2012 – months after their selection of NECC and purchase of the steroid drug from NECC – the SSC Defendants sold the steroid drug product to Plaintiffs during the course of Plaintiffs' injections. The product sold to Plaintiffs – the contaminated steroid – is what caused Plaintiffs' injuries. Each product sale of the steroid to Plaintiffs is governed by the PLA. Plaintiffs' PLA claims therefore constitute “product liability actions” under the PLA because they arise from harm caused by a **product** related to the **sale** of product to patients in August and

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<sup>45</sup> Put differently, plaintiffs' claims under the TPLA could be maintained regardless of whether the doctor here satisfied the standard of care because as a “seller” of an “unreasonably dangerous” product, the SSC Defendants became subject to the TPLA.

September 2012, not the quality of **services** provided by any defendant or the wisdom of the defendants' decision to purchase from NECC in July 2012.

By contrast, a cause of action under the HCLA turns on whether the defendant medical provider breached a duty of care to the plaintiff, and in so doing caused injury to the plaintiff.<sup>46</sup> Here, in June 2012, the Tennessee Defendants chose NECC as its supplier of the steroid drug and began purchasing it from NECC without patient specific prescriptions. If, as Plaintiffs allege, those actions by the Tennessee Defendants violated the relevant standard of care, then those Defendants can be held liable under the HCLA for injuries legally caused by those breaches of the standard of care.

To put it another way, the PLA and HCLA statutes (and the associated claims) apply to different transactions in the timeline of events – the HCLA applies to the Tennessee Clinic Defendants' negligent selection of NECC as the supplier of the steroid drug (a decision made in July 2012) and their unlawful purchase of it from NECC, while the PLA applies to the actual sale of that steroid drug product to the Plaintiffs in August and September 2012 in connection with each scheduled procedure, as reflected in this timeline of events:

**June 2012**

Defendants' selection  
of NECC as supplier  
of steroid drugs

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HCLA applies

**August/Sept 2012**

Defendants' sale of steroid  
drug product to Plaintiffs

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PLA applies

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<sup>46</sup> Tenn. Code Ann. § 29-26-102(b).

Accordingly, the two statutes can be reconciled in a manner that gives meaningful effect to both. Therefore, there is no reason for the Court to find that the HCLA implicitly abrogated the PLA.

**E. The PLA is the More Specific Statute as it Relates to the Product Sale**

The PLA applies specifically to the sale of a product, without regard to any standard of care, and therefore is the more specific statute under the facts at issue here. As it relates to the claims at issue, the PLA is more specific to the sale of MPA by NECC than is the HCLA, which does not even make reference to product sales. Of course, the PSC acknowledges that the SSC Defendants' services in administering the injections, which are governed by a standard of care, as well as the SSC Defendants' decision purchase to MPA from NECC in the first place, which is also governed by a standard of care. Again, the PSC's position is not that the Court's decision is an "either/or" application of the HCLA and PLA. Instead, the PSC's position is that the Court must find that the SSC Defendants' sale of product of the Plaintiffs – which SSC's own witness admitted occurred – gives rise to an independent claim under the PLA, separate and apart from the HCLA claim.

Indeed, if the Court were to find that the HCLA simply swallows all claims "related to" the medical industry, then the Court effectively would be abrogated the silicone gel breast implant exception in the PLA. As explained above, that exception indicates that *other* providers of medical services (those providers other ones offering silicone gel breast implant services) *are* "sellers" under the PLA, and therefore that the PLA otherwise applies to them. The defendants essentially urge the Court to abrogate the PLA's language by implication, which is only a position of last resort. By contrast, the PSC offers a position that gives meaning to the PLA's terms (including the silicone gel breast implant exception) and the HCLA's terms in a manner

that allows the PLA to apply specifically to the type of transaction (a product) that the PLA contemplates and addresses – and on which the HCLA is noticeably silent.

**F. The Legislative History and Policy Considerations Support the PSC's Position**

**1. Legislative History Shows the Tennessee Legislature Intended for the HCLA and PLA to Be Construed Harmoniously**

It is clear that the Tennessee Legislature intended the HCLA and the PLA to operate harmoniously, because the Legislature worked on both statutes simultaneously as part of the same Act, the Civil Justice Act of 2011 (“CJA”). As part of the CJA, the Tennessee Legislature both enacted the HCLA and rewrote the PLA.<sup>47</sup> The Tennessee Legislature therefore considered both statutes at the same time (amending one, enacting the other) and saw no conflict.<sup>48</sup> If it had seen such a conflict, the legislature could have abrogated the PLA, or otherwise indicated how such a conflict should be resolved, in the same Civil Justice Act that created the HCLA. But it did not.

**2. Policy Considerations**

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<sup>47</sup> See 2011 Tenn. HB 2008, 2011 Tenn. Pub. Acts 510 (enacted June 16, 2011). With respect to the PLA, the Civil Justice Act of 2011 amended PLA § 104 (Tenn. Code Ann. § 29-28-104), relating to damages, and PLA § 106 (Tenn. Code Ann. § 29-28-106), which relates to the conditions under which a “seller” can be held liable under the PLA at the same time. Effectively, in its amendments to PLA § 106, the Tennessee legislature authorized lawsuits against “sellers” as defined in § 102(7), provided that (among other things) the manufacturer of the product at issue was insolvent.

<sup>48</sup> This is contrary to the misleadingly incomplete version of the legislative history offered by the Tennessee Defendants, who state that the HCLA was enacted after the PLA, but fail to mention that the HCLA was enacted in the very same piece of legislation that rewrote the PLA. [Dkt. 2463 at 21].

As a policy matter, the Tennessee system is unique and logical.<sup>49</sup> The system makes manufacturers liable for injuries caused by their products in the first instance; but if the manufacturer is judgment proof or cannot be served, then the next entity in the chain is liable to the victim, regardless of the industry and the nature of the product at issue. The statutory scheme arguably provides beneficial incentives to Tennessee-based medical providers: they can limit their potential liability by purchasing drugs and other medical products from **appropriately capitalized** and **appropriately insured** companies. Indeed, clinics and hospitals are generally in a better position to absorb the cost of purchasing a bad product from an undercapitalized pharmaceutical company (such as NECC) than are innocent victims.

In other words, when the manufacturer of a pharmaceutical product sold to patients cannot make the victims of a unreasonably dangerous or defective products whole, the legislature was faced with determining whether (a) to make victims whole by authorizing them to sue medical providers who sold and administered the product to them, or (b) to let victims be left without a make-whole remedy on strict products liability grounds. The Tennessee legislature chose the latter approach, except with respect to a narrow carve-out relative to medical providers of silicone gel breast implants.

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<sup>49</sup> Of course, it is the province of the Tennessee Legislature – not the courts – to make policy judgments concerning the scope of the THCLA and the TPLA. *See Smith v. Gore*, 728 S.W.2d 738, 747 (Tenn. 1987) (“All questions of policy are for the determination of the legislature, and not for the courts . . . . Where the courts intrude into their decrees their opinions on questions of public policy, they in effect constitute the judicial tribunals as lawmaking bodies in usurpation of the powers of the legislature.”) (quoting *Cavender v. Hewitt*, 239 S.W.767, 768 (1921)). However, given that the Saint Thomas Defendants argued that the Tennessee system was illogical and made no policy sense, the PSC anticipates that the SSC Defendants will do the same and, therefore, addresses policy considerations in this section.

In the present case, the SSC Defendants ignored the incentives created by the PLA at their own peril: they purchased MPA from a manufacturer that was not sufficiently capitalized or insured. They did so simply because NECC offered a “good price.” In so doing, the SSC Defendants assumed the responsibility under the PLA to make innocent victims of contaminated products whole if and when NECC were declared insolvent. Had the SSC Defendants taken the simple expedient of identifying an appropriately capitalized or appropriately insured provider of steroids (a large, FDA-approved drug manufacturer for example), it would not be faced with a strict products liability claim under the PLA for the severe injuries or deaths suffered by the Plaintiffs.

### **III. At a Minimum, the Motion Should Be Denied In Light of Changed Circumstances**

Even if the Court were inclined to grant the SSC Defendants’ motion on the merits based on the Court February 2016 Order and Opinion, the Court should refrain from doing so because the issue has already been certified to the Tennessee Supreme Court.

#### **A. Procedural Developments since the Court’s February 29, 2016, Order**

On June 16, 2016, Chief Judge Kevin Sharp of the Middle District of Tennessee certified to the Tennessee Supreme Court the questions at issue in the SSC Defendants’ motion. Judge Sharp, presiding over a declaratory judgment action brought by the SSC Defendants’ insurer, State Farm, over whether it must provide a defense or indemnity coverage to the SSC Defendants under their policy contract, certified the following questions to the Tennessee Supreme Court:

1. Can a patient maintain a strict products liability action against an ambulatory surgery center licensed under Tennessee Code Title 68, or a physician licensed under Tennessee Code Title 63, for an injury sustained during an epidural steroid injection procedure, given the definition of a “health care

liability action” under Tenn. Code Ann. § 29-26-101 and the burden of proof requirements established by Tenn. Code Ann. § 29-26-115?

2. Is an ambulatory surgery center, licensed pursuant to Tennessee Code Title 68, “engaged in the business of selling” the steroid administered during an epidural steroid injection procedure, so as to be strictly liable as a “seller” under Tenn. Code Ann. § 29-28-106?<sup>50</sup>

**B. Certification of the Determinative Question Here to the Tennessee Supreme Court Means It Cannot Be Decided As a Matter of Law.**

In his order certifying these questions, Judge Sharp explicitly recognized that the answers to these questions would potentially resolve not only the issues in the declaratory judgment action before him, but also the issues in the summary judgment motion before this Court here.<sup>51</sup> For that reason alone, SSC’s motion should be denied.

District Courts in Tennessee – as elsewhere – do not certify questions lightly. Tennessee Supreme Court Rule 23 permits a District Court for the United States in Tennessee to certify a question of law when the Court determines that (1) there is a question of law that is determinative of the cause, and (2) there is no controlling precedent in Tennessee Supreme Court decisions. “[F]ederal courts generally will not trouble our sister state courts every time an arguably unsettled question of state law comes across our desks. When we see a reasonably clear

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<sup>50</sup> Order Certifying Questions of Law to Tennessee Supreme Court under Tennessee Supreme Court Rule 23, *State Farm Fire and Casualty Co. v. Specialty Surgery Center, et al.*, No. 2:15-cv-00026, Dkt 115 (M.D. Tenn. Jun. 16, 2016), Exhibit T to Declaration of Benjamin Gastel.

<sup>51</sup> *Id.* n.5 (“An answer on the issue of the viability of the product liability claim will resolve all (or virtually all) of the issues in the declaratory judgment action in front of this Court. In the MDL, the Intervenor Plaintiffs (Plaintiffs with suits against another Tennessee clinic who purchased and administered MPA from NECC, Saint Thomas Outpatient Neurosurgical Center, LLC) have moved for summary judgment on the same issue. Thus, in addition to resolving the issues in the declaratory judgment action, answering this question will likely resolve the same issue in the MDL.”).

and principled course, we will seek to follow it ourselves.”<sup>52</sup> The dearth of cases addressing the interaction of product liability claims with the HCLA lead to the Middle District of Tennessee seeking guidance from the Tennessee Supreme Court.

Plaintiffs respectfully request that this Court, given the certification of these questions to the Tennessee Supreme Court, follow its prior precedent and deny the pending motion for summary judgment.<sup>53</sup>

Other federal courts, too, have denied summary judgment motions that raise unsettled questions of state law pending before a state’s highest court.<sup>54</sup>

As those courts recognized, denying summary judgment on unsettled questions of law that have been certified to the state supreme court is the proper and prudent course.<sup>55</sup> If the Court dismisses Plaintiffs’ PLA claims now, there looms the risk of unnecessary waste of the Court’s

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<sup>52</sup> *Carbon Processing & Reclamation, LLC v. Valero Mktg. & Supply Co.*, 823 F. Supp. 2d 786, 823-24 (W.D. Tenn. 2011) (quoting *Pennington v. State Farm Mut. Auto. Ins. Co.*, 553 F.3d 447, 450 (6th Cir. 2009)).

<sup>53</sup> See, e.g., *Single Source, Inc. v. Cent. Reg’l Tourism Dist., Inc.*, No. CIV.A. 08-40176-FDS, 2011 WL 1877700, at \*4 (D. Mass. May 17, 2011) (where court could find no controlling authority on the determinative questions of Connecticut law, summary judgment was denied and case stayed because “[t]he interests of comity and cooperative judicial federalism will be best promoted by affording the Connecticut Supreme Court the opportunity, in the first instance, to interpret a state statute”).

<sup>54</sup> See, e.g., *Patterson v. CitiMortgage, Inc.*, No. 1:11-CV-0339-CC, 2012 WL 4468750, at \*13 (N.D. Ga. Sept. 26, 2012) (denying defendants’ summary judgment motion where another court in unrelated case had certified to Georgia Supreme Court the same question at issue in case before court in this case), *aff’d in part*, 820 F.3d 1273 (11th Cir. 2016); *U.S. Fire Ins. Co. v. Pinkard Constr. Co.*, No. 09-CV-01854-MSK-MJW, 2010 WL 3632138, at \*1-2 (D. Colo. Sept. 10, 2010) (denying defendants’ summary judgment motion where another court in unrelated case certified to the Colorado Supreme Court the same question presented before court in this case).

<sup>55</sup> As this Court has noted, federal courts hearing diversity matters should be cautious about adopting innovative theories in state law absent some authoritative signal from the legislature or the state courts. *In re New England Compounding Pharmacy, Inc. Products Liab. Litig.*, 2014 WL 4322409, at \*15. Now that an authoritative signal from the Tennessee Supreme Court is pending, the Court should deny SSC’s motion and await that signal.

and the parties' time and resources if the Tennessee Supreme Court comes to the opposite conclusion and finds Plaintiffs PLA claims valid, thereby requiring the bellwether trials to be retried. To the contrary, there is no harm in the Court allowing the PLA claims to go to the jury here: as Plaintiffs explained previously, the evidence presented by Plaintiffs will be virtually the same for both, both causes of action can be addressed on the same jury verdict form, and no result reached by the jury would result in conflict or double recovery.

In sum, given the very issue that is the subject of SSC's motion is an open question certified to the Tennessee Supreme Court, it is the more prudent and efficient course to allow Plaintiffs' PLA claims to proceed, rather than risk the waste of time and resources required to retry the bellwether cases in the event the Tennessee Supreme court finds Plaintiffs may maintain their PLA claims against SSC. For these reasons, the PSC respectfully asks the Court to deny the SSC Defendants' Motion for Summary Judgment.

### **CONCLUSION**

The Court should deny the SSC Defendants' Motion on the merits. In the alternative, the Court should deny the motion because the issues underlying it have already been certified to the Tennessee Supreme Court.

Dated: July 20, 2016

By: /s/ Benjamin A. Gastel

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**CERTIFICATE OF SERVICE**

I, Benjamin A Gastel, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: July 20, 2016

/s/ Benjamin A. Gastel  
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